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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,548	01/07/2000	MATTHIJS P SMITS	103.28	3197
55409	7590	11/28/2005	EXAMINER	
MATTHEW J. TEMMERMAN 423 E. STREET DAVIS, CA 95616			FAULK, DEVONA E	
			ART UNIT	PAPER NUMBER
			2644	
DATE MAILED: 11/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/479,548

Applicant(s)

SMITS ET AL.

Examiner

Devona E. Faulk

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-34, 36-41, 43-52 and 54-58, 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54 is/are allowed.
- 6) ☒ Claim(s) 29-34, 36-38, 40-43, 45-47, 51-56 and 60-64 is/are rejected.
- 7) ☒ Claim(s) 39, 44, 48-50, 57 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/25/2005, with respect to the rejection(s) of claim(s) 28,29,31,33,35,40, 47,52 and 56 under 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Neely.
2. The examiner wants to address one argument asserted by the applicant. The examiner has withdrawn her rejections due to other arguments regarding the Thorton reference. The applicant's asserts that the claim limitations of claims 47,52 and 56 are directed to functions and method steps relating to detection of non-physiologic (asymmetric) noise separate from symmetric noise. The examiner point out that the applicant is arguing something that is not recited in the claim limitations. There is nothing in the claim limitations that speak to detection of non-physiologic (asymmetric) noise separate from symmetric noise. The claim limitations only speaker to determining a degree of polarity bias in noise, determining when said bias is excessive and accounting for any excessive bias.
3. The applicant's indicated that he submitted a terminal disclaimer to overcome the double patent rejection but the office does not have the terminal disclaimer on record. The examiner suggests the applicant resubmit the terminal disclaimer. The double patent rejection will be maintained until a terminal disclaimer is received and put in the record.
4. Claims 1-28,35,42,53,59 and 65 are cancelled.

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5. The indicated allowability of claims 34,36-38,41-43,51,60-63 is withdrawn in view of the newly discovered reference(s) to Neely, Feinland. Rejections based on the newly cited reference(s) follow.
6. Claim 54 remains in allowable form.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims **29-34,37,47,52,56,59 and 64** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1,3,6,7,8,33,34-38, 44 and 45** of U.S. Patent No.6,620,100. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identified claims of the application 09/479,548 disclose a device and method for evaluation of hearing loss that have the same functionality as claimed in the identified claims of U.S. Patent No. 6,620,100. Claims 28-35,37,42,47,52,53,56, and 59 are

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overall broader than the corresponding claims 1,3,6,7,8,33,34-38,44 and 45 and thus it would have been obvious that anything that infringed on the narrower claim.

Claim Rejections - 35 USC § 112

9. **Claims 33,34,40,47,52,56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33,40,47,52 and 56 recite "means for determining the polarity bias of said noise component" or "determining a degree of polarity bias in the noise", and "detecting the degree of polarity bias in said noise". The specification discloses determining or detecting the polarity bias in the EEG or ABR signal and using that data to determine or detect if excessive non-physiological noise is present (page 3, line 22-page 4, line 9; page 6, line 10-13; page 7, line 25-page 8, line 6). The specification teaches of detecting the degree of polarity in the response signal and that this polarity bias is associated with certain non-physiological noise sources (page 10, lines 10-12) but this does not equate to determining the polarity bias of said noise component. The examiner is interpreting the language of detecting the polarity bias of the noise component to detecting the polarity bias of the response signal.

10. **Claim 55** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 55 recites "wherein the step of accounting for excessive

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amounts of said noise comprises rejecting a portion of said array of polarity sums". The specification teaches of rejecting the latest block of sweeps (page 4, lines 17-21).

11. **Claims 60-62 and 38** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 60 and 61 recite "wherein the ambient acoustic noise is sampled both before and during the time the auditory stimulus is delivered" and "wherein the ambient acoustic noise is sampled before the auditory stimulus is delivered" and "wherein the ambient acoustic noise is sampled during the time the auditory stimulus is delivered respectively. Claim 38 recites "taking samples of the ambient acoustic noise both before and during the time that the auditory stimulus is delivered". The specification discloses that during evaluation the ambient acoustic signal undergoes signal conditioning (page 12, lines 9-13). The examiner did not see that the specification taught of the ambient acoustic noise being sampled both before and during the time of the auditory stimulus or only before the time of the auditory response.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **Claims 29-31,33, 40, 41,43,45,47,51 and 52** are rejected under 35

U.S.C. 102(b) as being anticipated by Neely et al. (US 5,697,379).

Claims 29,31 share common features.

Regarding **claims 29 and 31**, Neely discloses a device for hearing evaluation of a subject (Figure 1) comprising:

means for repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62);

means for sampling an EEG response to said stimulus (DSP, 18, Figure 1; column 6, lines 63-65) and

means for detecting when non-physiological noise (residual noise) is associated with EEG responses (computer 20; column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46;column 15, lines 25-32; column 24, claim 38, lines 31-54).

Regarding claim 31, Neely further discloses means for automatically determining the amount of said non-physiological noise, and for automatically determining when said amount is excessive relative to a threshold (column 24, claim 38, lines 62-64)

Regarding **claim 30**, Neely disclose comprising means for indicating when said non-physiological noise has been detected (column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46;column 24, claim 38, lines 31-54).

Regarding **claim 41**, Neely teaches of further comprising means for determining the presence of an ABR waveform (DSP, 18; column 3, lines 38-54).

14. Regarding **claim 43**, Neely discloses a method for hearing evaluation of a subject comprising the steps of :

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repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62; reads on repeatedly delivering an auditory stimulus of claims 43,60-62);

measuring the EEG response to said stimulus (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35; reads on measuring the EEG response of claims 60-62)

detecting the noise associated with said EEG response (column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46;column 24, claim 38, lines 31-54; reads on determining the signal energy of said ambient acoustic noise of claims 60-62);

automatically determining that said amount is excessive relative to a threshold (residual noise; column 8, line 44- column 9, line 18; column 24, claim 38; reads on determining if said signal energy exceeds a predetermined threshold of claims 60-62);

wherein automatically determining that said noise amount is excessive relative to a threshold comprises computing a composite signal noise variance (column 8, lines 50-55).

Regarding **claim 45**, Neely teaches of further comprising the step of determining the presence of an ABR waveform (DSP, 18; column 3, lines 38-54).

15. **Claims 33,40,47 and 52** share common features.

Regarding **claims 33,40,47 and 52**, Neely discloses a hearing device for hearing evaluation of a subject comprising:

Means for repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62; reads on repeatedly delivering an auditory stimulus of claims 40,52,47 and on a transducer having an audible click output stimulus of claim 64);

Means for sampling an EEG response to said stimulus, said EEG response including a noise component (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35; reads on means for sampling an EEG response of claim 40, measuring EEG responses of claim 47);

Means for determining the polarity bias of said noise component (computer 20; column 6, lines 34-41; column 8, line 44- column 9, line 18; claim 38; reads on determining a degree of polarity bias of claim 47 and 52); and

Means for detecting the degree of polarity bias in said noise component and for determining when said bias is excessive relative to a threshold (computer 20; column 6, lines 34-41; column 8, line 44- column 9, line 18; column 24, claim 38; reads on determining when said bias is excessive of claim 47 and detecting the noise associated with said EEG response of claim 52).

Regarding **claim 51**, Neely teaches of further comprising the step of determining the presence of an ABR waveform (DSP, 18; column 3, lines 38-54).

16. Regarding **claim 62**, Neely discloses a method for hearing evaluation of a subject comprising the steps of :

repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62);

measuring the EEG response to said stimulus (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35)

detecting the noise associated with said EEG response (column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46; column 24, claim 38, lines 31-54);

automatically determining that said amount is excessive relative to a threshold (column 8, line 44- column 9, line 18; column 24, claim 38);

wherein the ambient acoustic noise is sampled during the time the auditory stimulus is delivered (column 5, line 65-column 6, line 30).

17. Regarding **claim 64**, Neely discloses a system for hearing evaluation of a subject comprising:

a transducer having an audible click output stimulus (32, earphone figure 1; column 6, lines 60-62);

an electrode system adapted to detect an EEG response to said stimulus (10,12, figure 1; column 6, lines 10-15); and

a processor (computer 20) , responsive to said EEG response, having
means for sampling an EEG response (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35);

means for processing the sampled EEG response and identifying therein a noise component and an evoked ABR component (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35); and

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means for automatically determining when said noise component contains a non-physiological component (computer 20; column 6, lines 34-43; lines column 8, line 44- column 9, line 18; column 24, claim 38; reads on determining when said bias is excessive of claim 47 and detecting the noise associated with said EEG response of claim 52).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. **Claims 32 and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over ~~anticipated by~~ Neely et al. (US 5,697,379) in view of Thorton et al. (US 4,275,764).

Regarding **claims 32 and 34**, Neely fails to disclose but Thorton teaches of wherein said threshold is derived from normative data. Thorton teaches that a decision is made as to whether the subject is responding by selecting a statistical confidence limit (See abstract), which reads on threshold derived from normative data; Normative is defined as of, relating to a norm or standard. It would have been obvious to modify Neely so that the threshold data is derived from normative data as taught by Thorton in order to better determine whether a subject is responding to the auditory stimulus.

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20. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Neely et al. (US 5,697,379) in view of Keefe (US 5,792,072).

Regarding **claim 36**, Neely discloses hearing device for hearing evaluation of a subject comprising:

Means for repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62; reads on repeatedly delivering an auditory stimulus of claims 43,60-62);

Means for sampling an EEG response to said stimulus Means for sampling an EEG response to said stimulus, said EEG response including a noise component (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35; reads on, measuring EEG response of claims 43,60-62);

Means for detecting ambient acoustic noise associated with said EEG response (column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46;column 24, claim 38, lines 31-54);

determining the signal energy of said ambient acoustic noise, and for determining if said signal energy is excessive relative to a threshold (column 8, line 44- column 9, line 18; column 24, claim 38, lines 60-63; amplitude is related to the signal energy).

Neely teaches of an earphone that implicitly detects some degree of ambient acoustic noise.

Neely fails to disclose but Keefe teaches wherein the means for detecting the ambient acoustic noise is a microphone (microphone, 30. figure 2; abstract discloses a

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microphone inserted in the ear). It would have been obvious to modify Neely by using a microphone to detect ambient acoustic noise in order to determine the linear and non-linear responses of the ear.

21. **Claims 60-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Neely et al. (US 5,697,379) in view of f the applicant's admitted prior art.

Regarding **claims 60 and 61**, Neely discloses a method for hearing evaluation of a subject comprising the steps of :

repeatedly delivering an auditory stimulus (32, earphone Figure 1; column 6, lines 60-62; reads on repeatedly delivering an auditory stimulus of claims 43,60-62);

measuring the EEG response to said stimulus (computer 20, column 6, lines 34-43; column 24, claim 38, lines 30-35; reads on measuring the EEG response of claims 60-62)

detecting the noise associated with said EEG response (column 2, lines 3-9; column 8, lines 26-30; column 14, line 49- column 15, line 46; column 24, claim 38, lines 31-54; reads on determining the signal energy of said ambient acoustic noise of claims 60-62);

automatically determining that said amount is excessive relative to a threshold (column 8, line 44- column 9, line 18; column 24, claim 38; reads on determining if said signal energy exceeds a predetermined threshold of claims 60-62).

Neely teaches of sampling the ambient acoustic noise during the time the auditory stimulus is delivered.

Neely fails to disclose but the applicant's admitted prior art teaches of wherein the ambient acoustic noise is sampled both before and during the time the auditory stimulus is delivered (page 3, lines 7-14).

Regarding claim 61, the applicant's admitted prior art teaches of sampling before the auditory stimulus is delivered (page 3, lines 7-14).

It would have been obvious to sampled both before and during the time the auditory stimulus is delivered in order to have a pre-set threshold to which EEG responses are compared.

22. **Claim 63** is rejected under 35 U.S.C. 103(a) as being unpatentable over Neely et al. (US 5,697,379) in view of Feinland et al. (US 5,226,496).

Regarding **claim 63**, Neely teaches of sampling the data but fails to disclose but Feinland teaches of sampling during three, approximately 20-millisecond windows of time (column 7, lines 15-23). It would have been obvious to modify Neely to sample as taught by Feinland in order to determine weights in a fast manner.

Claim Objections

23. **Claims 39,44,48-50,57-58** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

24. **Claim 54** is allowed.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to method or device for hearing evaluation:

U.S. Patent 6,475,163 to Smits et al. discloses a hearing evaluation device with patient connection evaluation capabilities.

U.S. Patent 6,343,230 to Smits et al. discloses a hearing evaluation device with predictive capabilities.

U.S. Patent 5,601,091 to Dolphin discloses audiometric apparatus and association screening method.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devona E. Faulk whose telephone number is 571-272-7515. The examiner can normally be reached on 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vivian Chin can be reached on 571-272-7848. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DEF



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